Marjorie E. Powell
Assistant General Counsel

PhRMA

May 18, 1999

Docket Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane - Room 1061
Rockville, Maryland 20852

RE: May 1999 FDA Compounding Advisory Committee Meeting

Dear Sir/Madam:

PhRMA would like to express its appreciation to FDA for the staff work in preparing for, and providing training to the members of, the FDA Compounding Advisory Committee at the Committee's second meeting. We understand from reviewing the agenda and listening to reports from Committee members, that FDA staff provided the Committee members with an overview of several aspects of the regulations governing INDs, NDAs, the manufacturing and marketing of approved drugs, and the post-marketing surveillance system for prescription drugs. This information is, in PhRMA's view, essential to informed decision-making by members of the Advisory Committee. Indeed, we understand that the briefings provided to Committee members enabled them to understand, and ask questions of, some of the people presenting information on specific substances being considered by the Committee. Your responsiveness to the PhRMA suggestion of January 22, 1999, is appreciated.

Sincerely,

Marjorie E. Powell

cc: Igor Cerny, CDER
Jane Axelrad, CDER

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